



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 12, 2020

Heather Bjornson-Lam
Regulatory Consultant to Veltek Associates, Inc.
Veltek Associates, Inc.
15 Lee Boulevard
Malvern, PA 19355

Subject: Label Amendment: Emerging Viral Pathogens Claim
Product Name: HYPO-CHLOR Neutral 0.25%
EPA Registration Number: 68959-11
Application Date: 5/19/2020
Decision Number: 563142

Dear Ms. Bjornson-Lam:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Because you have opted to add statements pertaining to emerging viral pathogens to your label as described in the August 19, 2016, Guidance to Registrants: Process For Making Claims Against Emerging Viral Pathogens Not On EPA-Registered Disinfectant Labels ("Guidance"), https://www.epa.gov/sites/production/files/2016-09/documents/emerging_viral_pathogen_program_guidance_final_8_19_16_001_0.pdf, you are subject to the following additional terms of registration:

1. You may make statements pertaining to emerging viral pathogens only through the following communications outlets: technical literature distributed exclusively to health care facilities, physicians, nurses and public health officials, "1-800" consumer information services, social media sites and company websites (non-label related). These statements shall not appear on marketed (final print) product labels.

2. Your statements pertaining to emerging viral pathogens must adhere to the format approved on the Agency-accepted master label.
3. You may make statements pertaining to emerging viral pathogens only upon a disease outbreak that meets all the following criteria:
 - a. The causative organism must be a virus that causes an infectious disease that has appeared in a human or animal population in the U.S. for the first time, or that may have existed previously but is rapidly increasing in incidence or geographic range.
 - i. For human disease, the outbreak is listed in one of the following Centers for Disease Control (CDC) publications:
 - A. CDC Current Outbreak List for “U.S. Based Outbreaks” (www.cdc.gov/outbreaks),
 - B. CDC Current Outbreak List for “Outbreaks Affecting International Travelers” with an “Alert” or “Advisory” classification (www.cdc.gov/outbreaks) (also released through the CDC’s Health Alert Network (HAN) notification process)
 - C. Healthcare-Associated Infections (HAIs) Outbreaks and Patient Notifications page (www.cdc.gov/hai/outbreaks)
 - ii. For animal disease, the outbreak is identified as an infectious disease outbreak in animals within the U.S. on the World Organization for Animal Health (OIE) Weekly Disease Information page (www.oie.int/wahis_2/public/wahid.php/Diseaseinformation/WI).
 - A. The CDC or OIE has identified the taxonomy, including the viral family and/or species, of the pathogen and provides notice to the public of the identity of the emerging virus that is responsible for an infectious disease outbreak. Based on the taxonomy of the outbreak pathogen identified by the CDC or OEI, the pathogen's viral subgroup is large non-enveloped and enveloped.
 - B. The virus can be transmitted via environmental surfaces (non-vector transmission), and environmental surface disinfection has been recommended by the CDC, OIE or EPA to control the spread of the pathogen.
4. You may begin communicating statements pertaining to emerging viral pathogens only upon CDC or OIE’s publication per term 3.a. of an outbreak of an emerging viral pathogen meeting all of the criteria of term 3. You must cease and remove all such non-label communications intended for consumers no later than 24 months after the original publication of the outbreak per term 3.a., unless the Agency issue written guidance to the contrary due to continued public health concerns. The emerging pathogen claim language may remain on the master label.

5. Terms from points 1 through 4 above shall become immediately void and ineffective if registration for use against Poliovirus Type 1 (ATCC VR-1562) is suspended or cancelled or no longer meets the criteria for a disinfectant claim (see EPA Product Performance Test Guideline 810.2200). In addition, terms B.1 through B.4 above shall become immediately void and ineffective upon your receipt of evidence of ineffectiveness against any pathogen in a less-resistant Spaulding category.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. If you have any questions, you may contact the disinfectants list at disinfectantslist@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'iD L', with a long horizontal stroke extending to the right.

Demson Fuller, Product Manager 32
Regulatory Management Branch I
Antimicrobials Division (7510P)
Office of Pesticide Programs

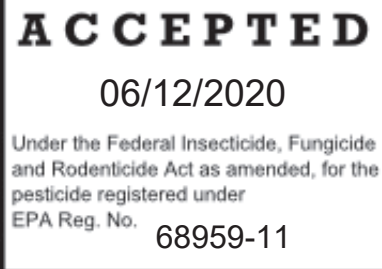
Enclosure: stamped label



Veltek Associates, Inc.

{Front Panel}

HYPO-CHLOR® NEUTRAL 0.25%
For Use in Clean Rooms and Controlled Areas
Hard Surface Disinfectant
Germicidal
***Virucidal**
[Aseptically Filtered at 0.2 µm] [Sterile]
[Ready to Use After Mixing]



[Sodium Hypochlorite at 0.25% [in] [which includes] [formulated with] USP Water for Injection Quality Water]

Active Ingredients:

**Sodium Hypochlorite CAS# 7681-52-9.....0.25%

Other Ingredients:.....99.75%

Total100.00%

**After mixing a decrease in % of active ingredient is expected, use within 24 hours or discard any unused material.

KEEP OUT OF REACH OF CHILDREN
WARNING

{Note to reviewer: The following reference statements available for various packaging scenarios.}

[See [side] [other] [back] [case label] [panel] [and/or] [package insert] for [first aid] [precautionary statements] [directions for use] [additional precautions] [and] additional product information].]

[Refer to the primary case label for [additional] precautionary statements, directions for use, and additional product information]

[Peel [here] [back] for [Spanish and] additional information]

[See container for lot number and storage expiration date]

{Lot Label Sticker}	
Reorder {xxxxxxxxxxx}	{QR Code}
Lot: {xxxxxxx}	
EXP. {dd-MM-YYYY}	
Net Contents: {(XXX mL /L) on Container or on Case (XX/CASE, Container size (yyy))}	

Red dot indicates Sterile {will not appear on non-sterile packages} Rev. M#/YY ●{code}

US and Foreign Patents www.sterile.com/patents

Net Contents: (XX oz or gallons)



Veltek Associates, Inc.

EPA Reg. No.: 68959-11
EPA Est. No.: 68959-PA-1

Manufactured by:

Veltek Associates, Inc.
15 Lee Blvd., Malvern PA 19355 – 1234 USA
Tel: 610-644-8335
www.sterile.com

Made in USA

VAI {corporate logo}

{End of Front Panel}

{Side/Back Panel}

FIRST AID

If in Eyes:

If splashed in eyes, hold eye open and rinse slowly and gently with water for 15-20 minutes, Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

If on Skin or Clothing:

Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

If Inhaled:

Move person to fresh air. If person is not breathing, call 911 or an ambulance, and then give artificial respiration, preferably mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.

If Swallowed:

Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything to an unconscious person.

EMERGENCIES: In the case of emergency call: 1-866-928-0789 (toll free) or 1-215-207-0061

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

WARNING. Causes substantial but temporary eye injury. Causes skin irritation. Harmful if inhaled. Do not breathe spray mist. Do not get into eyes, on skin, or on clothing. Wear protective eye wear (goggles, face shield, or safety glasses), long-sleeved shirt and long pants, socks, shoes, and waterproof or chemical-resistant gloves. Wash thoroughly with soap and water after handling and before eating., drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

ENVIRONMENTAL HAZARDS: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.



PHYSICAL AND CHEMICAL HAZARDS: Contact with acid releases toxic chlorine gas. Do not mix this product with other chemicals.

DIRECTIONS FOR USE

Read the label before using.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is NOT to be used as a terminal sterilant / high-level disinfectant on any surface or instrument that (1) is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body, or (2) contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to pre-clean or decontaminate critical or semi-critical medical devices prior to sterilization or high-level disinfection.

LOCATIONS OF USE: Disinfects clean rooms and controlled areas such as those in health care institutions, biopharmaceutical, pharmaceutical, medical device and diagnostic manufacturing facilities. Use on hard non-porous, inanimate, surfaces in aseptic filling and gowning rooms, general manufacturing areas and laboratories or on: machinery, tools, tables, counters, laminar-flow benches, floors, walls, carts, shelves, made of plastic, glass, vinyl, glazed porcelain, laminates, glazed tile, and stainless steel. It is compatible with most non-porous hard surface materials.

PREPARE USE SOLUTION: Follow SimpleMix System Container instructions.

SimpleMix System Container Instructions:

[On (16 Ounce) Trigger Spray Bottle label:]

1. *To prepare use solution, open cap.*
2. *Peel off inner seal by grasping tab at far edge and pulling off.*
3. *Firmly push small, inner container [(completely) (all the way)] down.*
4. *Replace cap and tighten.*
5. *Slowly swirl for 15 seconds.*
6. *Move spray nozzle to open position.*
7. *Follow directions for use on label.*

[On 1 Gallon Size Bottle label:]

1. To prepare use solution, open cap.
2. Peel off inner seal by grasping tab at far edge and pulling off.
3. Firmly push small, inner container [(completely) (all the way)] down.
4. Replace cap and tighten.
5. Slowly swirl for 15 seconds.
6. Open small side spout and peel off inner seal, as above.
7. Pour solution from small side spout onto surfaces to be treated or alternate containers.
8. Follow directions for use on label.



[On 55 Gallon (200 L) Drum label: {Note to reviewer: to be used with customer supplied pump}]

1. Close all valves
2. Uncoil hoses.
3. Connect center hose to pump between X and Y.
4. Open valve 1, then valve 2, then valve 4.
5. START pump to empty cubic container.
6. When cubic container is empty, turn pump OFF.
7. Close valve 1 and valve 2.
8. Open valve 6 and valve 5.
9. Re-start pump and mix 15 minutes.
10. STOP pump.
11. Close valve 4.
12. To dispense – Open Valves 3 and 7. Run pump only when dispensing.
13. Follow directions for use on the label.

DISINFECTION: Pre-clean visibly soiled surfaces. Thoroughly wet surface with the prepared use solution and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes rinse and wipe dry with sterilized cloth wiper, if desired.

***VIRUCIDAL:** The results of AOAC Efficacy Tests show that HYPO-CHLOR Neutral 0.25% is an effective virucide on inanimate, non-porous non-food contact surfaces, in the presence of organic load, demonstrated in testing against **Human Adenovirus 5 (ATCC# VR-5)*, **Influenza A Virus, Strain A/ Hong Kong(ATCC# VR-1679)*, and **Poliovirus Type 1 (ATCC# VR-1562)* in 5 minutes.

Pre-clean visibly soiled surfaces. Thoroughly wet surface with the prepared use solution and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes rinse and wipe dry with sterilized cloth wiper, if desired.

SANITIZATION OF NON-FOOD CONTACT SURFACES: Pre-clean all surfaces. Thoroughly wet surface with the prepared use solution and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes, rinse and wipe dry with sterilized cloth wiper, if desired.

FUNGICIDAL: Pre-clean visibly soiled surfaces. Thoroughly wet surface with the prepared use solution and allow to remain wet for a minimum of 5 minutes. Allow surface to air dry, or after 5 minutes, rinse and wipe dry with sterilized cloth wiper, if desired.

{Note to reviewer: a similar statement is on the front panel so this information is a duplicate.}

Storage and Disposal

Do not contaminate water, food, or feed by storage and disposal.

Storage: Store in original container in a cool dry area away from direct sunlight and heat to avoid deterioration. In case of spill, flood area with large quantities of water.

Disposal: Product or rinsates that cannot be used must be diluted with water before disposal in a sanitary sewer. Follow Federal/Provincial/State regulations and Local/Municipal ordinances when disposing of this product. Improper disposal of excess product, spray mixture or rinsate is a violation of Federal/Provincial/State Laws. If these wastes cannot be disposed of by use

according to label instructions, contact your Federal/Provincial/State or Local/Municipal environmental control agency for guidance.

Container Handling: *(Note to reviewer: This product is not dilutable.)*

Non-refillable container. Do not reuse or refill this container to hold materials other than this product. [(For containers equal to or less than 5 gallons) Offer container for recycling if available and dispose of in a sanitary landfill, or by incineration.] or [(For containers greater than 5 gallons) Offer container for recycling if available, or reconditioning if appropriate, or dispose of in a sanitary landfill, or by incineration.].

{Note: To appear as label end panel for customer use on containers: convenience item.}

User Information
Date Opened/Operator:
<input type="text"/>
Expiration Date:
<input type="text"/>
Area:
<input type="text"/>

(Note to reviewer: Optional Visual to Ensure Customer Compliance with Directions)

{1 Gallon SimpleMix}





Veltek Associates, Inc.

{16 Ounces SimpleMix}

SIMPLE MIX SPRAY



(Logo)

HYPO-CHLOR[®]  NEUTRAL





Optional Label Claims

HYPO-CHLOR Neutral 0.25% is bactericidal. The results of AOAC Efficacy Tests show that HYPO-CHLOR Neutral 0.25% is an effective hard surface disinfectant on inanimate, non-porous non-food contact surfaces, in the presence of organic load, demonstrated in testing against *Pseudomonas aeruginosa* (ATCC# 15442), *Staphylococcus aureus* (ATCC# 6538), in 5 minutes.

HYPO-CHLOR Neutral 0.25% is an effective sanitizer on inanimate, non-porous non-food contact surfaces demonstrated in testing against *Staphylococcus aureus* (ATCC# 6538) and *Enterobacter aerogenes* (ATCC# 13048) in 5 minutes.

HYPO-CHLOR Neutral 0.25% is an effective fungicide on inanimate, non-porous non-food contact surfaces, in the presence of organic load, demonstrated by the results of AOAC Efficacy Tests against *Trichophyton interdigitale* (ATCC# 9533) in 5 minutes.



Emerging Viral Pathogens

This product qualifies for emerging viral pathogen claims per the EPA's 'Guidance to Registrants: Process for Making Claims Against Emerging Viral Pathogens not on EPA-Registered Disinfectant Labels' when used in accordance with the appropriate use directions indicated below.

This product meets the criteria to make claims against certain emerging viral pathogens from the following viral categories:

- Enveloped Viruses
- Large Non-Enveloped Viruses

<i>For an emerging viral pathogen that is a/an</i>	<i>...follow directions for use for the following organisms on the label</i>
Enveloped virus	Poliovirus Type 1 (ATCC VR-1562)
Large, non-enveloped virus	Poliovirus Type 1 (ATCC VR-1562)

Acceptable claim language:

[Product name] has demonstrated effectiveness against viruses similar to [name of emerging virus] on hard, non-porous surfaces. Therefore, [product name] can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [pathogen-specific website address] for additional information.

[Name of illness/outbreak] is caused by [name emerging virus]. [Product name] kills similar viruses and therefore can be used against [name of emerging virus] when used in accordance with the directions for use against [name of supporting virus(es)] on hard, non-porous surfaces. Refer to the [CDC or OIE] website at [website address] for additional information.